

**REMARKS**

**Formal Matters**

The title has been amended to reflect the subject matter presently under examination.

Claims 20-25, 27, 29 and 30 remain in this application. Claims 1-19, 26 and 28 and 31-73 have been previously canceled. No new matter is added by the amendments.

Support for the amendments is found throughout the specification, and specifically at page 5, lines 15-16 and Figure 6.

In view of the Examiner's earlier restriction requirement, applicants retain the right to present withdrawn and cancelled subject matter (e.g., claims 1-19, 26, 28 and 31-73), as well as unclaimed subject matter, in subsequent prosecution.

**The Rejection Under 35 U.S.C. § 101**

Claims 20 to 25, 27, 29 and 30 are rejected under 35 U.S.C. § 101, allegedly because they are drawn to an invention with no apparent or disclosed specific, substantial and credible utility for the reasons of record in the Office Action of 14 October 2005.

Specifically, the Examiner has asserted that the instant application allegedly does not disclose a specific, biological role for the claimed polypeptide or its significance to a particular disease, disorder or physiological process which one would manipulate for a desired clinical effect. In summary, the Examiner argues the following:

- (1) There is no experimental evidence, either in the specification or the prior art of record, that exogenous administration or agonist activation of a receptor can induce an inflammatory response;
- (2) There is no evidence of record indicating when induction of an inflammatory response would be desirable;
- (3) The alleged failure of the specification to provide the evidence of (1) and (2) is required to employ the claimed polypeptide in its currently available form in a process of identifying compounds having anti-inflammatory activity.

The Examiner also asserts that the submission of the Lee affidavit on 14 May 2006 that proteins of the instant invention would be useful in the identification of antagonists, which would be then expected to have anti-inflammatory activity - is deficient because the identification of such antagonists would first require the capacity to activate the receptor. Because the specification does not, the Examiner alleges, provide the guidance needed to activate the putative chemokine receptor protein described therein without first identifying the identity of at least one agonist of the receptor, the claimed protein is not useful in the identification of anti-inflammatory compounds in its currently available form.

In response, Applicants respectfully traverse the rejection.

Previously, Applicants have asserted that the polypeptides of the invention are proinflammatory and that antagonists of such polypeptides would be expected to have anti-inflammatory activity. This utility claim was based on the specification disclosure linking the claimed polypeptides to inflammation, as verified by contemporaneous publications in Stoeckle *et al.*, *New Biologist*, 1990, 2(4): 313-323, and corroborated by more recent references of Sabroe *et al.*, *Eur. Respir. J.* 2002, 19: 350-355, Luster *et al.*, *Nature Immunol.* 2005, 6(12): 1182-1190.

Applicants now assert that the specific, credible and substantial utility of the claimed polypeptides is as a marker for inflammation. While Applicants still maintain that the specification and evidence of record clearly establish and support the proinflammatory nature of the claimed polypeptides, for reasons of prosecution expediency - Applicants now submit that such evidence establishes a compelling case as a diagnostic marker of inflammation.

Diagnostic applications are explicitly enumerated in the specification at page 2, lines 25-26, page 4, lines 2-4, page 12, lines 4-5, page 49, lines 3-5, page 53, lines 8-12.

As set forth in the Second Declaration of James Lee ("Second Lee Declaration"), it is now widely understood that chemokines (such as the chemokine polypeptides of the invention) modulate inflammation through leukocyte trafficking. Second Lee Declaration, para. 7; Luster *et al.*, 2005, *Nat. Immunol.* 6(12): 1182-1190. Thus it follows, and one of ordinary skill would appreciate, that the presence of such chemokine polypeptides in a particular tissue sample,

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would be indicative of leukocyte migration, and hence inflammation. Second Lee Declaration, para. 9.

Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 20-25, 27, 29 and 30 under 35 U.S.C. § 101.

The Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 20-25, 27, 29 and 30 are rejected under 35 U.S.C. § 112, First Paragraph, as allegedly failing to teach how to use the invention for reasons similar to those recited under 35 U.S.C. § 101.

In response, Applicants arguments responsive to the rejection under 35 U.S.C. § 101 are dispositive of this rejection as well.

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**SUMMARY**

Claims 20-25, 27, 29-30 are pending in the application. Claims 1-19, 26, 28 and 31-73 are canceled without prejudice to later prosecution.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is strongly encouraged to call the undersigned at the number indicated below.

This response/amendment is submitted with a petition for a 3-month extension of time and fees. If additional fees are required in this filing, applicants authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,  
GENENTECH, INC.

Date: October 5, 2007

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